

PATENT COOPERATION TREATY



PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

Applicant's or agent's file reference	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/FR2004/000995	International filing date (day/month/year) 23.04.2004	Priority date (day/month/year) 25.04.2003
International Patent Classification (IPC) or national classification and IPC A61K47/48, A61K9/16, A61K9/14		
Applicant PIERRE FABRE MEDICAMENT et al.		

1.	This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2.	This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.
3.	This report is also accompanied by ANNEXES, comprising: <div style="margin-left: 20px;"> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <div style="margin-left: 20px;"> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> </div> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> </div>
4.	This report contains indications relating to the following items: <div style="margin-left: 20px;"> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement according to Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p> </div>

Date of submission of the demand 24.02.2005	Date of completion of this report 07.04.2005
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Box No. I. Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3 and 23.1(b)).
 - ☐ publication of the international application (under Rule 12.4).
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3).
2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, pages

1-12 as originally filed

Claims, No.

1-11 as originally filed

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:
 - ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)):
 - ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty	Yes	Claims	
	No	Claims	1-11
Inventive Step	Yes	Claims	
	No	Claims	1-11
Industrial Applicability	Yes	Claims	1-11
	No	Claims	

2. Citations and explanations (Rule 70.7)**see separate sheet**

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2.3 Claim 11 (product by process):

- (N) The subject matter of the independent claim 11 is not consistent with the criterion for novelty defined by Article 33(2) PCT.

The products (molecular complexes) which may be obtained by the method according to claim 1 are not different from the products obtained by the methods described in documents D1 to D5. Furthermore, they are not different from the molecular complexes disclosed in D6. Documents D1 to D6 therefore anticipate the subject matter of the present claim 11.

- (IS) The subject matter of the independent claim 11 does not involve an inventive step as defined by Article 33(3) PCT, for the reasons mentioned above.

- (PA) The subject matter of the independent claim 11 is susceptible of industrial application as defined by Article 33(4) PCT.

As regards point V

1. The relevant documents are identified as D1 to D8 in order of citation in the International Search Report (ISR).
2. Citations and explanations in support of the statement regarding the novelty (N), the inventive step (IS) and the possibility of industrial application (PA) (Rule 43a.1(a)(i) and 43a.1(b) PCT):

2.1 Claim 1 (method):

- (N) The subject matter of the independent claim 1 is not consistent with the criterion for novelty defined by Article 33(2) PCT.

Documents D1 to D5 anticipate methods for the preparation of molecular complexes using a molecular diffusion step comprising bringing a dense fluid under pressure (in particular supercritical CO₂) into contact, in static mode, with a mixture of a host molecule (in particular cyclodextrins) and an active substance which is insoluble in water, in the presence of a diffusion agent, especially water (see the relevant passages indicated in the ISR). Consequently, all the technical characteristics defined in the present claim 1 are anticipated in the state of the art.

The characteristic "dense fluid" defined in the present claim 1 does not limit the scope of the subject matter claimed in relation to documents D1 to D5 because a supercritical fluid as described in D1-D5 is effectively a "dense fluid".

- (IS) The subject matter of the independent claim 1 does not involve an inventive step as defined by Article 33(3) PCT, for the reasons mentioned above.
- (PA) The subject matter of the independent claim 1 is susceptible of industrial application as defined by Article 33(4) PCT.

2.2 Dependent claims 2-10:

The dependent claims 2-10 do not contain characteristics which, combined with the characteristics of any claim to which they refer, satisfy the PCT requirements in terms of novelty and inventive step (Article 33(2) and (3) PCT).